

Remarks:

In the Office Action dated May 5, 2005, claims 21-41, in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks. Claims 21-41 remain in this application and claims 1-20 have been canceled.

The disclosure was objected to due to spelling/clerical errors in claims 36, 39 and 41. The claims have been amended to correct these errors.

Claims 21-37, 40 and 41 were rejected under 35 USC §102(b) as anticipated by Canadian Pat. 2,093,946. Claims 21, 40 and 41 have been amended to recite the coating limitations of claims 38 and 39 which were not rejected. In view of these amendments applicants request that this rejection be withdrawn.

Claims 21-37, 40 and 41 were rejected under 35 USC §102(b) as anticipated by Canadian Pat. 2,149,052. Claims 21, 40 and 41 have been amended to recite the coating limitations of claims 38 and 39 which were not rejected. In view of these amendments applicants request that this rejection be withdrawn.

Claims 21-41 were rejected under 35 USC §103(a) as unpatentable over 2,149,052 in view of EP 0 421 921 A1 and Canadian Pat. 1,305,166. As discussed above, 2,149,052 does not disclose the coatings recited in the amended claims. EP 0 421 921 was cited for the disclosure of enteric coatings such as Eudragits. Applicants point out that enteric coatings release the drug in

the intestine not the stomach as in the present invention. EP 0 421 921 (U.S. 5,096,717) teaches pamidronate granules with two coatings. The inner coating (col. 5, lines 42 – 45) contains hydroxyl propylmethyl cellulose and the outer gastric juice resistant coating contains an acrylic acid-methacrylic acid copolymer (col. 5, lines 46-50). This is different from the present invention which does not use a double coating and is not enteric. Applicants point out that there are different forms of Eudragit and the different forms are not interchangeable due to their solubility. The Eudragit disclosed in EP 0 421 921 A1 does not dissolve during contact with digestive solution in the patient's stomach as in the present invention. Eudragit E, RL, RS and NE are either pH independent or are soluble in gastric fluid up to pH 5.0. However, Eudragit L, L 30D and S, which are disclosed in EP 0 421 921, solubilize above pH 6, 5.5 and 7 respectively.

Attached is a list which describes where the different forms of Eudragit deliver the coated drug. As shown on this list, Eudragit L delivers the drug in the jejunum, Eudragit L-30D delivers the drug in the duodenum and Eudragit S delivers the drug in the ileum. Therefore, applicants contend that EP 0 421 921 does not suggest or disclose the coating used in the present invention which dissolves or separates from the core in the patient's stomach. Canadian Pat. 1,305,166 does not disclose coated tablets and thus does not cure the deficiencies in EP 0 421 921 and 2,149,052. In view of the above discussion, applicants respectfully contend that none of the cited references disclose or suggest a method for treating bone disease by administering a formulation which contains ibandronate and a coating which dissolves or is separated from the core

during contact with digestive solution in the patient's stomach and request that this rejection be withdrawn.

Applicants respectfully submit that all of claims 21-41 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

By



Monica Chin Kitts
Attorney for Applicants
Registration No. 36,105
ROTHWELL, FIGG, ERNST & MANBECK, p.c.
Suite 800, 1425 K Street, N.W.
Washington, D.C. 20005
Telephone: (202)783-6040